AUG 2 0 2002

K022410

510(k) Summary of Substantial Equivalence

1. MANUFACTURER:

Genzyme Biosurgery
A division of GENZYME CORPORATION
600 Airport Road
Fall River, MA 02720

Contract: Karen K. Sylvia, Sr. Regulatory Specialist
Date Prepared: 22 July, 2002

2. DEVICE:

Tradename:	Saph-Loop™ Ligating Loop
Classification:	Nonabsorbable poly(ethylene terephthalate) surgical suture per 21 CFR § 878.5000.
Common Name:	Suture with integral Deployment Device

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence is the Tevdek® II suture currently marketed by Genzyme Biosurgery, Fall River, MA 02720 (K001440). This 510(k)for Tevdek® II NextStitch™ and "silky" II POLYDK® NextStitch™ Cardiovascular Valve Suture is a special configuration of Tevdek® II.

4. DEVICE DESCRIPTION:

Saph-LOOP is the addition of a means for deployment of a length of Tevdek™ suture with a pre-tied knot for ligation of conduit in minimally invasive and general procedures, particularly conduit harvesting procedures. The deployment device consists of a long tube carrier with an offset tip at the distal end, a handle and a pull ring at the proximal end.

5. INTENDED USE:

The Saph-Loop™ Ligating Loop is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

6. COMPARISON

The Saph-Loop™ Ligating Loop is a means to deploy a cut length of Tevdek® II with a pre-tied knot. The suture is the same suture as currently marketed by Genzyme Biosurgery with the addition of the carrier tubing and handle for deployment.

The determination of substantial equivalence for this device was based on a detailed device description, conformance to consensus standards and voluntary standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

Genzyme Biosurgery
Karen K. Sylvia
Senior Regulatory Specialist
600 Airport Road
Fall River, Massachusetts 02720

Re: K022410
Trade/Device Name: Saph-Loop™ Ligating Loop
Regulation Number: 878.5000
Regulation Name: Non-absorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 18, 2002
Received: July 24, 2002

Dear Ms. Sylvia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K022410

Device Name ***Saph-Loop™ Ligating Loop***

Indications for Use

The Saph-Loop™ Ligating Loop is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milleren

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022410

Prescription Use ✓ OR Over-the-Counter Use _
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)